

**SUMMARY OF SAFETY AND EFFECTIVENESS**

This summary of safety and effectiveness is being submitted in accordance with the requirements of The Safe Medical Devices Act of 1990 (SMDA 1990) and 21 CFR 807.92.

**I. GENERAL INFORMATION**

Date of Summary Preparation:	January 27, 2000
Distributor:	BRAHMS Diagnostica, LLC 29 South Peachtree Street Norcross, Georgia 30092
Manufacturer:	BRAHMS Diagnostica, GmbH Neuendorfstrasse 25 D-16761 Hennigsdorf Germany
Contact Person:	H. Lee Herron Partner BRAHMS Diagnostica, LLC 29 South Peachtree Street Norcross, Georgia 30092 Tel: 770-449-7738 Fax: 770-449-7739
Device Name:	LUMItest® anti-TPO <sub>n</sub>
Common or Usual Name:	Luminescence immunoassay kit for the determination of anti-thyroid peroxidase antibodies
Classification:	
Name:	Thyroid autoantibody immunological test system
Class	Class II
CFR:	21 CFR 866.5870
Substantial Equivalence To:	DYNOtest® anti-TPO <sub>n</sub>

**II. INTENDED USE**

LUMItest anti-TPO<sub>n</sub> is a competitive luminescence immunoassay for the quantitative determination of autoantibodies to thyroid peroxidase (TPO) in human serum using the coated tube technique. The LUMItest anti-TPO<sub>n</sub> kit is used as an aid in the diagnosis of Hashimoto's thyroiditis and Graves' disease, autoimmune diseases affecting the thyroid gland.

### III. DEVICE DESCRIPTION

LUMItest anti-TPO<sub>n</sub> is a competitive luminescence immunoassay intended for the quantitative determination of autoantibodies against thyroid peroxidase in human sera using a coated tube technique. A mouse monoclonal antibody against thyroid peroxidase bound to the solid phase competes with autoimmune anti-thyroid peroxidase antibodies in patient samples, standards and controls for indirectly labeled native human thyroid peroxidase which is added to the test tubes. The indirect label consists of a luminescent labeled (acridinium ester) monoclonal antibody against a separate epitope on the added thyroid peroxidase. Following incubation, unreacted, labeled monoclonal antibody and unreacted thyroid peroxidase are washed from the tube and luminescence bound to the tube is measured in a luminometer. The measured luminescence is inversely proportional to the quantity of anti-thyroid peroxidase antibody in the sample.

### IV. COMPARISON TO PREDICATE DEVICE

The LUMItest® anti-TPO<sub>n</sub> immunoassay kit is similar to the BRAHMS Diagnostica DYNOfest anti-TPO kit (K992791) in the indications for use, format, solid phase, performance characteristics and results. The LUMItest anti-TPO<sub>n</sub> test differs from the DYNOfest anti-TPO<sub>n</sub> only in the signal. . In the LUMItest anti-TPO<sub>n</sub> assay, a luminogenic molecule, acridinium ester, is used to replace the <sup>125</sup>I signal used in the DYNOfest anti-TPO<sub>n</sub> assay.

Substantial equivalence to the DYNOfest anti-TPO<sub>n</sub> kit cleared under K992791 is based on clinical comparison using 509 serum samples from normal blood donors (n=300) and patients with Graves' disease, Hashimoto's thyroiditis and non-autoimmune thyroid disease (n=209). Overall agreement of both groups based on a 2 X 2 agreement table was 507/509 = 99.6%.

		DYNOfest anti-TPO	
LUMItest Anti-TPO		Positive	Negative
	Positive	184	2
	Negative	0	323

% Agreement = 99.6%

This correlation study demonstrates that the LUMItest anti-TPO<sub>n</sub> assay is substantially equivalent to the legally marketed predicate device, BRAHMS Diagnostica DYNOfest anti-TPO assay.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

MAR 17 2000

Mr. H. Lee Herron  
Partner  
BRAHMS Diagnostica, LLC  
29 South Peachtree Street  
Norcross, Georgia 30092

Re: K000287  
Trade Name: LUMItest<sup>®</sup> anti-TPO<sub>n</sub>  
Regulatory Class: II  
Product Code: JZO  
Dated: January 28, 2000  
Received: January 31, 2000

Dear Mr. Herron:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

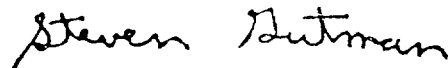
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive, slightly slanted style.

Steven I. Gutman, M.D., M.B.A.  
Director  
Division of Clinical Laboratory Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

1. **Indications for Use Statement**

**510(k) Number (if known):** K000287

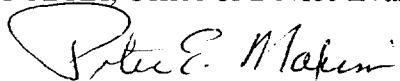
**Device Name:** LUMItest anti-TPO<sub>n</sub>

**Indications For Use:**

LUMItest anti-TPO<sub>n</sub> is a competitive luminescence immunoassay for the quantitative determination of autoantibodies to thyroid peroxidase (TPO) in human serum using the coated tube technique. The LUMItest anti-TPO<sub>n</sub> kit is used as an aid in the diagnosis of Hashimoto's thyroiditis and Graves' disease, autoimmune diseases affecting the thyroid gland.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of Clinical Laboratory Devices

510(k) Number K 000287

Prescription Use ☒  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ☐